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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Intellectual Property Dept.
Dewitt Ross & Stevens SC
2 East Mifflin Street
Suite 600
Madison, WI 53703-2865

EXAMINER	
HELM, CARALYNNE E	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
10/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

Office Action Summary	Application No.	Applicant(s)	
	10/567,979	Al-LAMEE ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-20 and 22-24* is/are pending in the application.

5a) Of the above claim(s) *10-20 and 23* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-9,22 and 24* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 17, 2011 has been entered.

Election/Restrictions

To summarize the current election, applicant elected Group I and the species where Formula I is poly(vinylbutyral-co-vinylalcohol-co-vinylacetate) with a Mw from 50,000 to 80,000, and 88% vinylbutyral groups and Formula II is poly(vinylpyrrolidone-co-vinylacetate) with an average Mw of 50,000. (It is noted that the restriction requirement did not require specification of the polymers' molecular weights). Groups I and IV were rejoined.

Claims 10-20 and 23 stand as withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-7, 9, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (previously cited) as evidenced by Dhaliwal et al.

(previously cited), Flick (Cosmetics Additives Noyes Publications:Park Ridge 1991 p304), and Stegbauer et al. (US Patent No. 5,324,615).

Whitbourne et al. teach a coating for implantable medical devices that is composed of both polymers and a bioactive agent (see abstract). Specifically the coating is envisioned to contain a bioactive agent, stabilizing polymer, and hydrophilic polymer (see column 3 lines 50-52). The hydrophilic polymer is preferably polyvinylpyrrolidone (PVP) or polyvinylpyrrolidone-co-vinyl acetate (PVP/VA) (second compound) and the stabilizing polymer is preferably polyvinylbutyral (first compound), where BUTVAR® B-79 is an envisioned variety (see column 3 lines 21-26, 32, and 43-44 and column 5 line 66-column 6 line 1 and 25-26; instant claims 1 and 22). Stegbauer et al. teach that BUTVAR® B-79 has a molecular weight of about 50,000 to about 80,000 with a composition (x, y, and z) of about 70 mol% vinyl butyral, about 28 mol% vinyl alcohol and about 2 mol% vinyl acetate (see column 9 line 61-column 10 line 1; instant claims 5 and 6). When converted to weight basis, this polymer has a composition with about 87 wt% vinyl butyral, about 11 wt% vinyl alcohol and about 2 wt% vinyl acetate (as calculated by the examiner – see instant claims 7). Dhaliwal et al. teach that polyvinylbutyral is a random terpolymer of vinyl butyral, vinyl alcohol and vinyl acetate (see page 245 column 2 paragraph 2-246 column 1 line 9; instant claims 1 and 22). Whitbourne et al. name E-635 and E-335 from GAF Corporation as envisioned varieties of PVP/VA suitable for the invention (see column 3 lines 43-44). Flick teaches that the vinyl pyrrolidone to vinyl acetate molar ratio (m and n) in E-635 is 60 to 40 while that of E-335 is 30 to 70 (see page 304; instant claims 1 and 22). Example 14 of

Whitbourne et al. teaches a stabilizing polymer, a bioactive agent, and a hydrophilic polymer where the latter is PVP/VA. Here the stabilizing polymer (polyamide and epoxy; first compound) to hydrophilic polymer (second component) ratio is 69 to 31 while the ratio of vehicle (stabilizing agent + hydrophilic polymer) to bioactive agent is 9 to 1 (see instant claims 3, 9, and 24).

Although Whitbourne et al. do not provide an example that combines their envisioned polyvinylbutyral and PVP/VA with a bioactive agent, it would have been obvious to one of ordinary skill in the art at the time of the invention to follow their teachings and combine the preferred stabilizing polymer and hydrophilic polymer along with a bioactive agent to prepare their coating for its touted flexibility and adhesion to the device substrate. It additionally would have been obvious to follow the suggestion of proportions according to example 14 where BUTVAR® B-79 is the stabilizing polymer and the PVP/VA is the suggested E-635 or E-335. This modification would yield a composition with a first compound and second compound as claimed and at the claimed proportions as well as a vehicle to bioactive ratio of 9 to 1. Since applicants have not defined the bounds for the term "about" the composition of these polymers and proportions are sufficient to meet the instant claim limitations. Applicants do not teach any additional structure or components in the a coating in order for it to be “configured to release bioactive material” when the device on which it is coated is implanted; therefore the coating of Whitbourne et al. as evidenced by Stegbauer et al., Flick, and Dhaliwal et al. which contain the claimed first compound, second compound and bioactive material at the recited proportions meets this limitation. Therefore claims 1-3,

5-7, 9, 22, and 24 are obvious over Whitbourne et al. as evidenced by Stegbauer et al., Flick, and Dhaliwal et al.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. as evidenced by Stegbauer et al., Flick, and Dhaliwal et al. as applied to claims 1-3, 5-7, 9, 22, and 24 above, and further in view of Sass (previously cited).

Whitbourne et al. as evidenced by Stegbauer et al., Flick, and Dhaliwal et al. make obvious a coating composition with a vehicle and bioactive as claimed. Whitbourne et al. teach that the coating is envisioned for stents and that bioactive agents can be selected based upon the effect that is desired (see column 2 lines 31-34 and column 3 lines 52-59). This modified reference does not explicitly teach the inclusion of 17β-estradiol as the bioactive agent.

Sass teaches that 17β-estradiol is known to inhibit smooth muscle cell growth and is used to inhibit restenosis and in-stent stenosis (see column 2 lines 50-57; instant claim 8).

Since Whitbourne et al. teach the inclusion of compounds that achieve a desired effect and the inhibition of restenosis would be desired for stents, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 17β-estradiol in the coating composition Whitbourne et al. as evidenced by Stegbauer et al., Flick, and Dhaliwal et al. as the simple substitution of one known element for another with a predictable outcome. Therefore claim 8 is obvious over Whitbourne et al. in view of Sass as evidenced by Stegbauer et al., Flick, and Dhaliwal et al.

Claims 1-7, 9, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. as evidenced by Stegbauer et al., Flick and Dhaliwal et al. as applied to claims 1-3, 5-7, 9, 22, and 24 above, and further in view of Khanna et al. (US Patent No. Re 34,990)

Whitbourne et al. as evidenced by Stegbauer et al., Flick, and Dhaliwal et al. make obvious a coating composition with a vehicle and bioactive as claimed. This modified reference does not explicitly teach the molecular weight of the PVP/VA which acts as the second compound.

Khanna et al. teach PVP/VA as a hydrophilic polymer in a drug delivery device that has 60% vinylpyrrolidone and 40% vinyl acetate by weight with a molecular weight of 60,000 ± 15,000 (see column 5 lines 38-43). The teaching of 60,000 ± 15,000 is interpreted as equivalent to the claimed “about 50,000” (see instant claim 4). This composition corresponds to a molar ratio (m and n) of 0.5 to 0.5 (as calculated by the examiner - see instant claims 1 and 22).

The proportion of monomers in the PVP/VA envisioned by Whitbourne et al. spans a range that includes 50/50 and such a compound was also known to serve as a hydrophilic polymer in a drug delivery composition as is also desired by Whitbourne et al. Consequently, it would have been obvious to one of ordinary skill in the art at the time of the invention to select the PVP/VA of Khanna et al. for the hydrophilic polymer in the invention of Whitbourne et al. as evidenced by Stegbauer et al., Flick, and Dhaliwal et al. This modification would have been obvious as the simple substitution of one

known element for another to yield a predictable result. Therefore claims 1-7, 9, 22, and 24 are obvious over Whitbourne et al. in view of Khanna et al. as evidenced by Stegbauer et al., Flick, and Dhaliwal et al.

Response to Arguments

Applicants' arguments, filed May 17, 2011, have been fully considered but they are moot in light of the new grounds of rejection.

All previous grounds of rejection are hereby withdrawn in light of the amendment to the claims. New grounds of rejection detailed above meet the limitations of the claims in their current form.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634